Formal Matters

The Examiner objected to the disclosure because allegedly the claims appear to rely on the use of a novel deposit. *See*, Paper No. 7, Page 2, Paragraph 2.

Applicants respectfully disagree and traverse.

Applicants submit that the claims rely upon the deposit identified as ATCC Accession No. 97304, deposited Sept. 25, 1995, which is the same deposit as supported by the specification as filed, on page 7, last full paragraph. Accordingly, Applicants respectfully submit that the Examiner's objection has been obviated, and therefore respectfully request that the objection be withdrawn. A copy of the ATCC deposit receipt is included with the Declarations submitted herewith.

Restriction Requirement

The Examiner withdrew claim 57 from consideration as being directed to a non-elected invention. *See*, Paper No. 7, Page 2, Paragraph 5.

Applicants disagree and traverse this restriction.

The subject matter of claim 57 is a compound which activates or inhibits the activity of the isolated protein molecule of claim 35 by activating or inhibiting a receptor for said polypeptide. Maintenance of claim 57 within Group II is proper, as many activators and/or inhibitors of the receptor may be minor variants of the claimed polypeptide itself. Accordingly, Applicants respectfully request that the Examiner withdraw the restriction requirement and rejoin claim 57 to the elected invention.

Rejections Under 35 U.S.C. § 112, Second Paragraph

The Examiner rejected claims 38, 45-46, and 55 under 35 U.S.C. § 112, second paragraph, as allegedly "indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention." *See*, Paper No. 7, Page 3, Paragraph 4. Specifically, the Examiner rejects claims 38 and 55, "and any other similar claims or claims that depend", as being broader than the claim from which they depend. The Examiner particularly points to the fact that "claim 37 refers to an encoded sequence of 2-92, but claim 38 requires an encoded sequence of 1-92." *See,* Paper No. 7, Page 3. Furthermore, the Examiner alleges that claims 45 and 46 are duplicates of claims 37 and 38, respectively.

Applicants respectfully disagree and traverse these rejections.

Preliminarily, Applicants have considered the Examiner's statement "[c]laim [sic] and any other similar claim or claims that depend," but are unsure as to exactly which claims, other than claims 38 and 55, the Examiner refers. *See,* Paper No. 7, Page 3. Accordingly, Applicants respectfully request that the Examiner clarify the claims, other than claims 38 and 55, to which this rejection is directed.

However, as the rejection applies to claims 38 and 55, claim 37 is directed to an isolated polypeptide comprising amino acids 2 to 92 of SEQ ID NO:2, while claim 38, which depends from claim 37, is directed to an isolated polypeptide comprising amino acids 1 to 92 of SEQ ID NO:2. Applicants assert that the subject matter of claim 37, while constituting a smaller polypeptide portion of SEQ ID NO:2 when compared to that of claim 38, is in fact broader in scope. Claim 38 is narrower in scope than claim 37 because it contains the further limitation of additional amino acid residues of SEQ ID NO:2, and accordingly is proper.

Claim 55, alternatively, is an independent claim containing a Markush group consisting of polynucleotides encoding polypeptides comprising both amino acids 1 to 92 and 2 to 92 of SEQ ID NO:2 as members. There is no dependency amongst members of the Markush group. Relating to Markush groups, the M.P.E.P. states in pertinent part that "claims of diminishing scope should not, in itself, be considered a sufficient basis for objection to or rejection of claims." M.P.E.P. § 2173.05(h). Thus, Applicants assert that the rejection of claim 55 as indefinite, as being broader than the claim it depends from, is improper.

The Examiner also rejected claims 45 and 46, contending that they are duplicates of claims 37 and 38, according to M.P.E.P. § 706.03(k).

Applicants respectfully disagree and traverse.

Claims 45 and 46 are product by process claims. The M.P.E.P. states in pertinent part that "[a] product-by-process claim, which is a product claim that defines the claimed product in terms of the process by which it is made, is proper." M.P.E.P. § 2173.05(p). By contrast, the subject matter of pending claims 37 and 38 is directed to human Chemotactic Cytokine I ("CC I") polypeptide compositions made by any process (*e.g.*, chemical synthesis or recombinant technology, see, for example, page 13, lines 23-24).

Accordingly, Applicants respectfully request reconsideration and withdrawal of the indefiniteness rejection of claims 38, 45-46, and 55 under 35 U.S.C. § 112, second paragraph. Applicants have demonstrated that claim 38 is narrower in scope than claim 37 which it depends from, and is therefore proper. Applicants have also demonstrated that claim 55

constitutes a proper Markush claim, and accordingly a rejection of claim 55 is improper. Furthermore, Applicants have shown that pending claims 46 and 46 are directed to products made by a process, in contrast to pending claims 37 and 38, and are therefore fully definite.

The Examiner rejected claims 35(b) at parts I, ii, and iii and claims 47(b) at parts I, ii, and iii as allegedly indefinite in the use of "at least" because the use of this phrase allegedly fails to recite an upper limit. The Examiner also rejected part b(iii) of each of claims 35 and 47 as also indefinite in the recitation of 5% because the specification allegedly does not teach a specific method for determining such." *See,* Paper No. 7, Page 4.

Applicants respectfully disagree and traverse these rejections.

As an initial matter, because claim 35 lacks a subpart (b) and parts I, ii, and iii, and claim 47 lacks parts I, ii, and iii, applicants respectfully request clarification as to which specific portions of the recited claims the Examiner rejects.

As to the Examiner's rejection of claim 35 as allegedly indefinite in the use of "at least," Applicants submit that the use of "at least" in claim 35 is definite, and is fully supported by the specification as filed, for example, at page 14, third full paragraph. Applicants submit that the use of "at least" in claim 35 is a limitation tied to SEQ ID NO:2, and thus the claimed polypeptide comprises a minimum of 30 amino acids of SEQ ID NO:2, up to and including the full sequence of SEQ ID NO:2. Applicants further submit that the Examiner's rejection of claims 35 and 47 on the basis of the recitation of 5% is improper because no where in the rejected claims do the Applicants utilize such a percent identity limitation.

However, Applicants have incorporated a percent identity limitation in pending claim 55. Applicants respectfully submit that the term "percent identity" is fully definite, as "percent identity" is a well known term of the art. Accordingly, Applicants respectfully submit that the rejection of claims 35 and 47 under 35 U.S.C. § 112, second paragraph, has been obviated and therefore request reconsideration and withdrawal of the rejections of claims 35 and 47 under 35 U.S.C. § 112, second paragraph.

Rejections Under 35 U.S.C. § 112, First Paragraph

The Examiner rejected claims 44 and 54 under 35 U.S.C. § 112, first paragraph, as allegedly based on a disclosure which is not enabling. Specifically, the Examiner alleges that a recovery step or a purification step critical or essential to the practice of the invention, but

not included in the claim(s), is not enabled by the disclosure. *See*, Paper No. 7, Page 3, Paragraph 3.

Applicants respectfully disagree and traverse this rejection.

Claim 44 is directed to composition subject matter, and hence an additional element of a recovery step or a purification step is not necessary in order for this claim to be proper. Claim 54 is a product-by-process claim, and claim 54 *specifically does* contain the limitation of a recovery step. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection or alternatively further clarification of the rejection in light of the above remarks.

The Examiner also rejected claims 35, parts b(I) to b(iii), and claim 35 (d), under 35 U.S.C. § 112, first paragraph, as allegedly not reasonably providing enablement for "a.) the upper limit of 'at least one or more deletions, substitution, or insertions; b.) nor for the enablement for 5% for the various modifications; c.) nor the any variants [sic]."

Applicants respectfully request clarification of the rejection. Claim 35 recites only "a polypeptide comprising at least 30 contiguous amino acid residues of SEQ ID NO:2," and does not recite deletions, substitutions, insertions, or variants. Additionally, claim 35 does not recite any percent identity limitation, thus it is unclear why this claim was rejected by the Examiner on enablement grounds for "the enablement for 5% for the various modifications." Furthermore, Applicants are unable to determine what the Examiner intends by "parts b(I) to b(iii), and part (d)." *See,* Paper No. 7, Page 4, Line 21. Finally, Applicants respectfully point out that claim 35 is directed to polypeptides, and thus Applicants are unsure why the Examiner's discussion of the rejection focuses on polynucleotides. *See*, Paper No. 7, Page 5.

Accordingly, Applicants respectfully request clarification of this rejection, and Applicants believe that they have addressed the rejections under 35 U.S.C. § 112, first paragraph, presented by the Examiner.

Rejections under 35 U.S.C. §§ 102 and 103

The Examiner rejected claims 35-56 and 59 under 35 U.S.C. § 102(a) or (b) as allegedly anticipated by Hitomi (D49548 or D49549), or Hillier et al (R02721 or R02722), or in the alternative, as allegedly being obvious over Hitomi (D49548 or D49549), or Hillier et al (R02721 or R02722), in view of Liao et al. or Hara et al.

Applicants respectfully disagree and traverse these rejections.

Genbank Accession Nos. D49548 and D49549 appear to have become publicly available on March 9, 1995, and Genbank Accession Nos. R02722 and R02721 appear to have become publicly available on March 31, 1995.

Submitted herewith is a copy of a Declaration by each of the Inventors of the present application under 37 C.F.R. § 1.131. The Declaration was originally submitted in the course of prosecution of the present application's parent application (*i.e.*, U.S. Application No. 08/761,289). The Declaration demonstrates possession of the claimed invention prior to the publication of any of the cited references; *i.e.*, prior to March 9, 1995. The Inventors demonstrate that they were in possession of cDNA clone "HALTA54" (which was later deposited at the ATCC as Accession No. 97304), that they had sequenced the human cDNA insert contained within the "HALTA54" clone therefrom, and that they had used the polynucleotide *to produce the encoded protein* in a baculovirus expression system, all prior to March 9, 1995, and all in the United States.

Because Applicants have clearly demonstrated possession of the claimed invention prior to the publication date of each of the cited references, rejection of claims 35-56 and 59 as anticipated, or in the alternative, as obvious in view of the cited references has been obviated. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejections of claims 35-56 and 59 under 35 U.S.C. §§ 102(a) or (b) and 103 in view of the comments made above and the Declaration submitted herewith.

Conclusion

In view of the foregoing remarks, Applicants believe they have fully addressed the Examiner's concerns and that this application is now in condition for allowance. An early notice to that effect is urged. A request is made to the Examiner to call the undersigned at the phone number provided below if any further action by Applicants would expedite allowance of this application.

If there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

Dated: April 2, 2001

Joseph J. Kenny (Reg. No. 43,710)
Agent for Applicants

Human Genome Sciences, Inc.
9410 Key West Avenue
Rockville, MD 20850
Telephone: (301) 610-5800
Facsimile: (301) 309-8439

Enclosured
MMW/JJK/RL/lcc

4-5-01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Jian Ni et al.

Application Number: 08/761,289 | Group Art Unit: 1646

Filed: December 6, 1996 | Examiner: G. Draper

Title: CHEMOTACTIC CYTOKINE I | Attny. Docket No. PF210

DECLARATION OF JIAN NI, GUO-LIANG YU, PEDRO ALFONSO, JEFFREY SU, AND REINER GENTZ UNDER 37 C.F.R. § 1.131

Assistant Commissioner of Patents
Washington, D. C. 20231

Sir:

Each of the inventors in the captioned application, Jian Ni, Guo-Liang Yu, Pedro Alfonso, Jeffrey Su, and Reiner Gentz declare and state as follows:

1. I am an inventor of the subject matter described and claimed in the above-identified U.S. patent application, which is assigned to Human Genome Sciences, Inc. (HGS). The work described below occured at HGS which is located in Rockville, Maryland, USA.

2. The above-identified patent application relates to the isolation and characterization of a cDNA encoding a novel gene product designated Chemotactic Cytokine I (CC)-I.

3. A cDNA clone designated "HALTA54" (479,617), was deposited with the American Type Culture Collection (ATCC) on September 25, 1995 and was assigned ATCC Accession No. 97304 (*See* Exhibit A). Exhibit B, attached hereto, is a redacted printout of data from IRIS (the HGS electronic documentation system), which shows the nucleotide sequence (No. 479,617) corresponding to cDNA clone HALTA54. The "Date Sequenced" redacted from Exhibit B is prior to March 09, 1995. Exhibit C, attached hereto, is a redacted printout of a Batch Worksheet which evidences expression of the protein encoded by clone HALTA54 in a baculovirus expression system. The redacted date upon which this Batch Worksheet was generated is prior to March 09, 1995.

4. The nucleotide sequence disclosed in Exhibit B corresponds to the sequence disclosed in Figure 1 of the above-identified application and U.S. Provisional Application Serial No. 60/008,387, a copy of which is attached herewith as Exhibit D and E, respectively. The only

differences between the sequence shown in Exhibit B and the identical sequences shown in Exhibits D and E is the exclusion from Exhibits D and E of the initial two G nucleotides and the final G nucleotide (ie., nucleotides 1,2 and 483) shown in Exhibit B. The cDNA clone HALTA54 (ATCC Deposit No. 97304) and Exhibit B both contain the entire sequence shown in Exhibits D and E.

5. I declare further that all statements made in this Declaration are of my own knowledge and are true and that all statements made on information and belief are believed to be true and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated: 1/7/99

Jian Ni

Dated:_____

Guo-Liang Yu

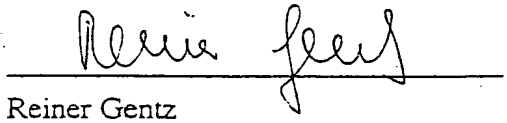
Dated:_____

Pedro Alfonso

Dated:_____

Jeffrey Su

Dated: 1/11/99



Reiner Gentz

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Jian Ni et al.

Application Number: 08/761,289 Group Art Unit: 1646

Filed: December 6, 1996 Examiner: G. Draper

Title: **CHEMOTACTIC CYTOKINE I** Attny. Docket No. PF210

DECLARATION OF JIAN NI, GUO-LIANG YU, PEDRO ALFONSO, JEFFREY SU, AND REINER GENTZ UNDER 37 C.F.R. § 1.131

Assistant Commissioner of Patents
Washington, D. C. 20231

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Dated:_____

_____
Jian Ni

Dated: 1/12/99

_____
Guo-Liang Yu

Dated:_____

_____
Pedro Alfonso

Dated:_____

_____
Jeffrey Su

Dated:_____

_____
Reiner Gentz

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Dated:_____ _____
Jian Ni

Dated:_____ _____
Guo-Liang Yu

Dated:_____ _____
Pedro Alfonso

Dated: 1/15/99 _____
Jeffrey Su

Dated:_____ _____
Reiner Gentz

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Jian Ni et al.

Application Number: 08/761,289 Group Art Unit: 1646

Filed: December 6, 1996 Examiner: G. Draper

Title: CHEMOTACTIC CYTOKINE I Attny. Docket No. PF210

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Dated:_____ _____
Jian Ni

Dated:_____ _____
Guo-Liang Yu

Dated: 1-25-99 _____
Pedro Alfonso

Dated:_____ _____
Jeffrey Su

Dated:_____ _____
Reiner Gentz

Exhibit A

American Type Culture Collection

12301 Parklawn Drive • Rockville, MD 20852 USA • Telephone: (301)231-5520 Telex: 398-055 ATCCNORTH • FAX: 301-770-1537

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF
THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3
AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

To: (Name and Address of Depositor or Attorney)

Human Genome Sciences
Attention: Robert H. Benson
9410 Key West Avenue
Rockville, MD 20850

Deposited on Behalf of: Human Genome Sciences

Identification Reference by Depositor:	ATCC Designation
DNA Plasmid, 751448 (Docket PF212)	97300
DNA Plasmid, 751447 (Docket PF211)	97301
DNA Plasmid, 876255 (Docket PF223)	97302
DNA Plasmid, 379842 (Docket PF209)	97303
DNA Plasmid, 479617 (Docket PF210)	97304

The deposits were accompanied by: _ a scientific description _ a proposed taxonomic description indicated above.

The deposits were received September 25, 1995 by this International Depository Authority and have been accepted.

AT YOUR REQUEST:

X We will inform you of requests for the strains for 30 years.

The strains will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strains and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strain.

If the cultures should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace them with living cultures of the same.

The strains will be maintained for a period of at least 30 years after the date of deposit, and for a period of at least five years after the most recent request for a sample. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the cultures cited above was tested October 5, 1995. On that date, the cultures were viable.

International Depository Authority: American Type Culture Collection, Rockville, Md. 20852 USA

Signature of person having authority to represent ATCC:

Date: October 11, 1995

Frank Simione, Acting Director, Patent Depository

Exhibit B

Human Genome Sciences, Inc.
Sequence Worksheet
HALTA54P:

Sequence Information

Gene Name:

HGS Code: 479617

Sequence ID: HALTA54P

Library Name: Human Adult Liver

Library Catalog: H0147

Date Sequenced:

Lab Sequenced: HGS

Group ID: 20190

Class:

Date Scored:

Lab Scored: HGS

In Group: 35

Previous Class:

Search Results

Overlap	Score	Description

Sequence

LOCUS HALTA54P 483 bp XXX UPDATED
DEFINITION
ORIGIN

```
      1 GGCACGAGCA CCACTGCTGG CTTTTTGCTG TAGCTCCACA TTCCTGTGCA TTGAGGGGTT
     61 AACATTAGGC TGGGAAGATG ACAAAACTTG AAGAGCATCT GGAGGGAATT GTCAATATCT
    121 TCCACCAATA CTCAGTTCGG AAGGGGCATT TTGACACCCT CTCTAAGGGT GAGCTGAAGC
    181 AGCTGCTTAC AAAGGAGCTT GCAAACACCA TCAAGAATAT CAAAGATAAA GCTGTCATTG
    241 ATGAAATATT CCAAGGCCTG GATGCTAATC AAGATGAACA GGTCGACTTT CAAGAATTCA
    301 TATCCCTGGT AGCCATTGCG CTGAAGGCTG CCCATTACCA CACCCACAAA GAGTAGGTAG
    361 CTCTCTGAAG GCTTTTTACC CAGCAATGTC CTCAATGGAG GGGTCTTTTC TTTGCCTCAC
    421 CAAAACCCAG CTTGACCCCT GGGGGGAGTT AAGAGTTAAT AACCACACTT ACGGAAAGTT
    481 CTG
//
```

Sequence Notes

Exhibit C

HGS

Human Genome Sciences, Inc.

Batch Worksheet

HG04900-B1: Chemotactic Cytokine I

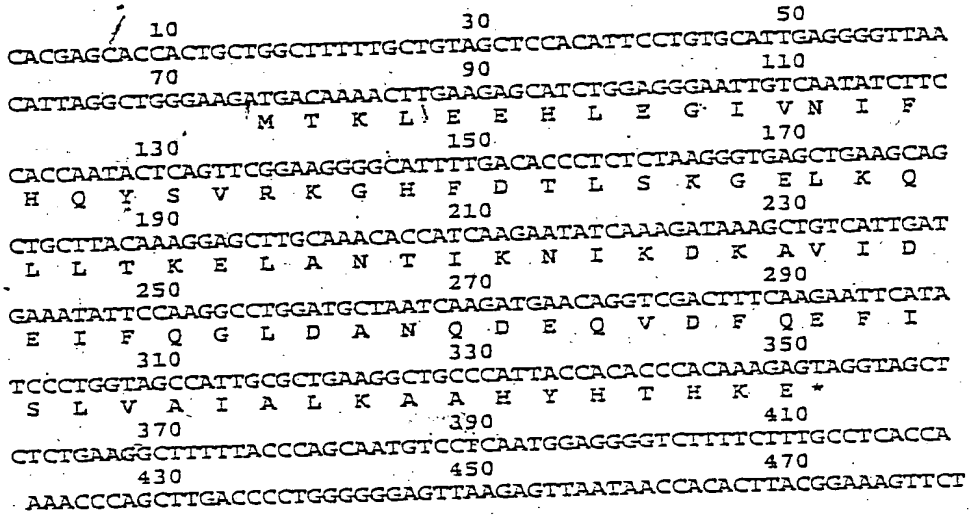
Gene Name: Chemotactic Cytokine I

Batch Serial #: HG04900-B1 Created: By:

Project Code: HG04900 Batch #: 1 Expression: Baculovirus

Qty Produced: 4.50 mg Qty Remaining: 2.50 mg

Date Sent	Sent To	mount	urity	Analysis	Inv ID
	Testing	1.00	95		133
	J. Ni	0.50	90		719
	J. Ni	0.50	90		720


10
30
50
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70
90
110
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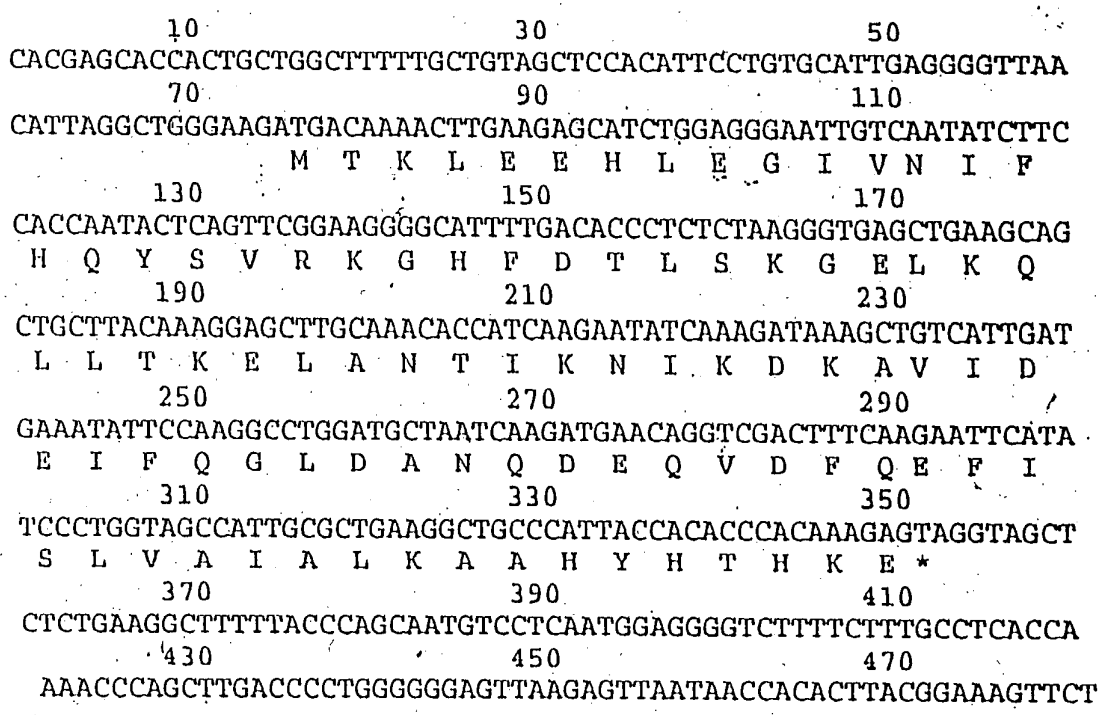
M T K L E E H L E G I V N I F
130
150
170
CACCAATACTCAGTTCGGAAGGGGCATTTTGACACCCTCTCTAAGGGTGAGCTGAAGCAG
H Q Y S V R K G H F D T L S K G E L K Q
190
210
230
CTGCTTACAAAGGAGCTTGCAAACACCATCAAGAATATCAAAGATAAAGCTGTCATTGAT
L L T K E L A N T I K N I K D K A V I D
250
270
290
GAAATATTCCAAGGCCTGGATGCTAATCAAGATGAACAGGTCGACTTTCAAGAATTCATA
E I F Q G L D A N Q D E Q V D F Q E F I
310
330
350
TCCCTGGTAGCCATTGCGCTGAAGGCTGCCCATTACCACACCCACAAAGAGTAGGTAGCT
S L V A I A L K A A H Y H T H K E *
370
390
410
CTCTGAAGGCTTTTTACCCAGCAATGTCCTCAATGGAGGGGTCTTTTCTTTGCCTCACCA
430
450
470
AAACCCAGCTTGACCCCTGGGGGGAGTTAAGAGTTAATAACCACACTTACGGAAAGTTCT

FIGURE 1 1/2

FIG. 1



American *Type Culture* Collection

12301 Parklawn Drive • Rockville, MD 20852 USA • Telephone: (301)231-5520 Telex: 898-055 ATCCNORTH • FAX: 301-770-2587

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF
THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3
AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

To: (Name and Address of Depositor or Attorney)

Human Genome Sciences
Attention: Robert H. Benson
9410 Key West Avenue
Rockville, MD 20850

Deposited on Behalf of: Human Genome Sciences

Identification Reference by Depositor:	**ATCC Designation**
DNA Plasmid, 479617 (Docket PF210)	97304

The deposits were accompanied by: _ a scientific description _ a proposed taxonomic description indicated above.

The deposits were received September 25, 1995 by this International Depository Authority and have been accepted.

AT YOUR REQUEST:

X We will inform you of requests for the strains for 30 years.

The strains will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strains and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strain.

If the cultures should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace them with living cultures of the same.

The strains will be maintained for a period of at least 30 years after the date of deposit, and for a period of at least five years after the most recent request for a sample. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the cultures cited above was tested October 5, 1995. On that date, the cultures were viable.

International Depository Authority: American Type Culture Collection, Rockville, Md. 20852 USA

Signature of person having authority to represent ATCC:

Frank Simione, Acting Director, Patent Depository

Date: October 11, 1995